

REMARKS

Applicants thank the Examiner for the courtesies extended during the interview of August 22, 2005, and for the Examiner's diligence with respect to providing the Interview Summary dated August 25, 2005. Applicants request that the Examiner carefully consider the foregoing amendments in light of the comments made during the interview and the remarks which follow.

Claims 1-40 and 58-69 are pending in the present application, claims 41-57 having been withdrawn from consideration by the Examiner. Mindful of the Examiner's position expressed in the August 22, 2005 interview, Applicants have amended claims 1-2, 6, 9, 11-13, 20, 23, 27, 30, 32-34, 41, 45-50 and 54-58 to recite aspects of the disclosed embodiments with more particularity. Support for the foregoing amendments is found throughout the present application, and certain specific examples are identified below. No new matter has been added.

Applicants intend to address the provisional double patenting rejection set forth at page 2 of the outstanding Office Action when the Examiner indicates that allowable subject matter has been recited in the present application.

As set forth in the outstanding Office Action, claims 17-19, 38-40, and 68 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Claims 1-40 and 58-69 stand rejected under 35 U.S.C. § 102(e) as anticipated by WO 01/31333 A1 to Milosavijevic et al. ("the '333 publication"). Claims 1-14, 20-35, 58-66, and 69 stand rejected under 35 U.S.C. § 102(e) as anticipated by WO 01/31317 A1 to Hogan et al. ("the '317 publication"). Additionally, claims 15-19, 36-40, 67, and 68 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the '317 publication.

Applicants address the definiteness of the claims and traverse the prior art rejection as set forth below. Applicants respectfully request reconsideration and allowance of all the pending claims in light of the following remarks.

Aspects of the present invention relate generally to a system and method of archiving and retrieving biological or non-biological samples maintained in desiccated form at a plurality of non-cross-contaminating discrete sample nodes on a carrier. Each "node" is a unitary structural element operative to maintain, carry, or otherwise to support a discrete sample as addressed, among other places, in the description of FIGS. 5A-5E beginning at page 31, line 24, and continuing to page 39, line 25, of the present application.

The Interview Summary

In the Interview there was a discussion of the Examiner's characterization of a "node" as evidenced in the outstanding Office Action and as succinctly articulated in the Interview Summary. The Examiner read the term "node" as encompassing an individual well in a microwell plate (microtiter plate) or even an individual test tube. Applicants pointed out that nodes claimed in the present Application are described in the Specification as non-contaminating discrete nodes and Applicants have amended the claims to replace the term "sample node" with the qualified term "discrete sample node." Applicants respectfully submit that, as amended, the claims can be read neither on a well in a microwell plate, nor on any other such container.

The term "discrete sample node" is described throughout the present application. In one example, elimination of contamination is identified as an advantage derived from aspects of the invention:

Cross contamination is virtually eliminated by storing the samples on discrete sample nodes 529. In some instances, sample nodes 529 may be optically separated from the sample carrier, thereby avoiding any mechanical contact involving a mechanical sample removal device during retrieval, extraction, purification, packaging, and shipping.

(page 34, lines 16-20).

From this and other examples, it is readily apparent that the pending application draws clear distinctions between a "discrete node," on the one hand, and a container, test tube, or well in a microwell plate, on the other hand. As set forth in the discussion spanning page 28, line 24 to page 31, line 3 (with specific reference to FIGS. 4A-4C) of the specification, a "node" as recited in the pending claims is described as a discrete or unitary structural entity that is entirely distinct from any sort of container into which the "node" is, or may be, deposited.

Further, as acknowledged by the Examiner at the interview, the claims of the present application require that each sample node is removably attached to a structural array at a respective attachment point. Applicants respectfully submit that the cited art does not describe such attachment points. Applicants submit with this Amendment, a declaration by Michael Hogan, co-inventor of the PCT patents described in the '333 and '317 publications, in which declaration Mr. Hogan affirms that attachment points are not described.

Finally, Applicants thank Examiner for acknowledging that, upon identification of allowable subject matter in the pending claims, rejoinder of method claims of similar scope would be considered.

Accordingly, Applicants affirm the position articulated during the interview that the prior art of record neither teaches nor suggested the nodes recited in the pending claims and request allowance of the pending claims and rejoinder of the withdrawn method claims.

The Rejection Under 35 U.S.C. § 112

As noted above, claims 17-19, 38-40, and 68 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants respectfully submit that an ordinarily skilled artisan, having read the specification in conjunction with an examination of the drawing figures, would readily be able to understand from the recitations of these claims what structure is intended by “derivatized.” For example the Specification provides:

“... sample support medium may be treated with one or more chemical compounds or derivatized, for instance, to manipulate various binding properties prior to contact with a specimen. Positive or negative electrical charges, chemical compositions, binding characteristics, antibodies, lectins, porosity, and other operational factors for sample nodes 529 may be selected in accordance with the type of sample support medium implemented and the type or nature of any processes performed thereon.”

Specification at page 33, lines 21-27. Accordingly, Applicants request that the rejection under 35 U.S.C. § 112 be withdrawn.

The Rejections Under 35 U.S.C. § 102(e)

As noted above, claims 1-40 and 58-69 stand rejected under 35 U.S.C. § 102(e) as anticipated by the ‘333 publication, and claims 1-14, 20-35, 58-66, and 69 additionally stand rejected under 35 U.S.C. § 102(e) as anticipated by the ‘317 publication. In order to anticipate a pending claim under any of the various subsections of 35 U.S.C. § 102, a reference must teach every element recited in the claim. As discussed during the interview and as set forth below, the fair teachings of the asserted publications are insufficient to anticipate the pending claims, and the rejections under 35 U.S.C. § 102(e) are therefore improper.

The cited publications are directed particularly to “punch card” systems as described in the present application in the discussion beginning at page 2, line 10, and continuing to page 3, line 11.

See, e.g., the descriptions at page 18, lines 6-11, of the '313 publication, and at page 4, lines 5-18, of the '317 publication. In accordance with the techniques taught in the cited publications, sample material is blotted onto a punch card substrate (designated by reference numeral 24 in FIG. 2) and diffuses through the substrate; this creates a universal or omnibus sample distributed across the substrate. A pellet or plug (designated by reference numeral 100 in FIG. 2) may be punched from anywhere on the substrate, irrespective of the uniformity of the sample material's diffusion, at a later time.

In contrast to the fair teachings of the cited publications, however, each discrete sample node described and claimed in the present application is operative to carry a "discrete" sample. In that regard, the present application does not specifically define the term "discrete" to mean anything more narrow than its ordinary usage suggests: *i.e.*, "separate" or "distinct." The punch card system taught in the cited publications must sever or excise a bit of sample material from an otherwise unified or consolidated substrate, and does not contemplate discrete samples as described and claimed in present application. The Examiner has identified this deficiency in the '317 publication as set forth on page 4 of the outstanding Office Action (acknowledging that the punch head assembly "punches out *a portion of the sample*"). Accordingly, a plug punched from a punch card, failing to carry a "discrete" sample as described and claimed in the present application, is not equivalent to a "discrete sample node" as recited in the pending claims.

As discussed above, it is readily apparent that the pending application draws clear distinctions between a "discrete node," on the one hand, and a container, test tube, or well in a microwell plate, on the other hand. As set forth in the discussion spanning page 28, line 24 to page 31, line 3 (with specific reference to FIGS. 4A-4C) of the specification, a "node" as recited in the pending claims is described as a discrete or unitary structural entity that is entirely distinct from any sort of container into which the "node" is, or may be, deposited.

Even assuming, *arguendo*, that the Examiner attempts to read the term "node" broadly enough to encompass such a plug *after it has been removed* from the substrate, Applicants note that the cited publications still fail to teach or even to suggest a structural array to which each of a plurality of discrete sample nodes is removably attached at a respective attachment point. As noted above, a co-inventor of the cited reference PCT patents has furnished a declaration supporting Applicants' position that the '333 and '317 publications do not describe, anticipate or render obvious the recited attachment points. See attached Declaration by Hogan.

Additionally, the substrate itself is not equivalent to the claimed nodes, at least for the following reasons. As set forth in the present specification in, among other places, the discussion at page 32, lines 1-18, a structural array “generally comprises a plurality of sample structures” which in turn are generally “maintained in a predetermined spatial relationship” and are operative to support sample nodes. The substrate disclosed in the cited publications neither includes such “sample structures” nor do the publications contemplate supporting nodes in a “predetermined spatial arrangement.” It is understandable that the cited publications are silent in this regard, since the sample material in the punch card system is distributed across the substrate, a plug may be removed from any location on the substrate.

Applicants submit that the cited publications fail to teach or to suggest at least the foregoing structural elements recited in every independent claim (claims 1, 20 and 58). Accordingly, the cited publications are insufficient to anticipate any of the pending independent claims, and the rejections of claims 1-40 and 58-69 under 35 U.S.C. § 102(e) are therefore improper. At least for the reasons set forth above with specific reference to independent claims 1, 20, and 58, their respective dependencies are also allowable. Further, claims 2-19, 21-40, and 59-69 recite additional features and combinations of elements, and Applicants submit that these claims are additionally allowable for their respective recitations as well.

The Rejections Under 35 U.S.C. § 103

As noted above, claims 15-19, 36-40, 67, and 68 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the ‘317 publication. Given the clear deficiencies of the ‘317 publication noted above, however, Applicants respectfully submit that the Examiner’s observations (at page 5 of the Office Action) regarding polymers, result effective variables, choice of surface derivatization, and charges, even if true, are not especially remarkable.

In particular, MPEP § 706.02(j) specifies that, in order for the Examiner to establish a *prima facie* case of obviousness, among other criteria, “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” Because the cited publications fail to teach every limitation recited in the independent claims as set forth in detail above, the Examiner has failed to establish a *prima facie* case of obviousness, and the rejection under 35 U.S.C. § 103(a) is improper.

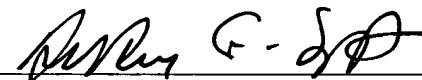
Accordingly, Applicants submit that the cited publications are insufficient to render obvious any of the pending claims, and request that the rejection of claims 15-19, 36-40, 67, and 68 under 35 U.S.C. § 103(a) be withdrawn.

Applicant believes that all claims are now in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (858) 509-4008.

Respectfully submitted,
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Dated: September 30, 2005

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I hereby certify that, on the date shown below, this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: September 30, 2005



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* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.